

Valued customer,

We are very pleased to announce that the following product is CE marked in conformity with the new European Medical Device Regulation (MDR, 2017/745).

- Hyaluronidase in FertiCult™ Flushing medium

CE marking of the product according to the MDR does result in the following changes:

- Use of 3-layered labels (For more information: [see previous newsletter](#))
- New version of instruction for use
- Endotoxin criterium is narrowed from <1 EU/ml to <0.5 EU/ml
- Carboard box as secondary packaging of product code HYA001

If additional information is required or additional registration actions in your jurisdiction(s), please send your question to ra@fertipro.com

In addition to the above,

we hereby inform you that the color of the screw cap of 10% PVP in FertiCult Flushing in chromacols, i.e. product code PVPO.2S has changed from white to blue. This change does not have any impact on the performance and safety of the product.



COMPANY ADDRESS

FertiPro nv
Industriepark Noord 32
B-8730 Beernem / Belgium

tel. +32 (0)50 79 18 05
fax +32 (0)50 79 17 99
info@fertipro.com
www.fertipro.com

RPR Brugge
VAT BE 0448 767 035
IBAN BE 98 7374 4024 9293
BIC KREDBEBB